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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,933	01/04/2002	Rohan Coelho	42390P11783	8489

7590 02/19/2009

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EXAMINER	
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ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
02/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/038,933	COELHO ET AL.	
	Examiner	Art Unit	
	Tran Nguyen	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

This communication is in response to the communication filed 12/30/2008. Pending claim(s): 1-24. Cancelled claim(s): 25-27. Amended claim(s): 1, 11, 16.

It is noted that the listing of the claims as filed on 12/30/2008 does not indicate the status of claims 25-27. Since claims 25-27 were originally presented and subsequently cancelled by preliminary amendment, Examiner considers claims 25-27 to be cancelled.

Additional clarification is requested.

Response to Amendment

The amendment filed 12/30/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The newly added limitation in claim 1 recites:

electronically communicating the health information between the portable healthcare device and a health professional device,

wherein communicating the health information includes one or more of prescribing prescriptions, accessing patient medical history, accessing medical test results, submitting order claims, purchasing medicine.

Claims 11, 16 recite similar limitations.

These newly added limitations appear to constitute new matter. Applicant did not point out, nor was Examiner able to find, any support for these newly added limitations in the specification as originally filed.

Applicant is requested to clarify the issues discussed above, to specifically point out support for the newly added limitations in the originally filed specification and claims to the extent possible, and to cancel any new matter in the reply to this Office Action.

Specification

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 USC 112, first paragraph for at least the same rationale as discussed above, and incorporated herein.

Claim Rejections - 35 USC § 112

Claim(s) 1-24 is/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As per claim(s) 1-24, these claims are rejected for at least the same rationale as discussed above, and incorporated herein.

NOTE: The rejection presented hereinbelow if for Applicant's consideration should Applicant properly traverses the new matter issues discussed above in the response hereto.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

As per claim 1, based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to a machine or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *In re Bilski* et al, 88 USPQ 2d 1385 CAFC (2008); *Diamond v.*

Diehr, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a statutory process, the claim should positively recite the particular machine to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state.

In particular, claim 1 recites a “method” comprising a plurality of steps performed by an “access server”.

In determining the scope of this limitation, the specification as originally filed on 01/04/2002 discloses (page 23):

[0074] Various software components, e.g. applications programs, may be provided within or in communication with the access server that cause the processor or other components of the server to execute the numerous methods employed in controlling access to health information from

Additionally, Merriam-Webster Online Dictionary defines "server" as " a computer in a network that is used to provide services (as access to files or shared peripherals or the routing of e-mail) to other computers in the network”.

When read in light of the specification and the level of ordinary skill in the art, Examiner interprets “server" to recite a computer or processor based on the specification and the definition afforded by Merriam-Webster Online Dictionary.

Therefore, because the claim positively recites a “machine” performing each method step, this claim is found to be directed towards statutory subject matter.

As per claims 2-10, these claims are also found to be directed towards statutory subject matter for at least the same rationale above, and incorporated herein.

As per claim 11, this claim positively recites a “system” comprising “a server computer having a processor and a storage medium coupled with the processor”.

Therefore, this claim is found to be directed towards hardware embodiments, and is found to be statutory.

All claims dependent thereon, namely claims 12-15, are also found to be directed towards statutory subject matter for at least the same rationale above, and incorporated herein.

As per claim 16, this claim recites "a machine-readable medium comprising instructions which, when executed, cause a machine to” perform a method.

As such, this claim is interpreted to recite a manufacture containing thereon functional descriptive material, and is found to be directed towards statutory subject matter.

All claims dependent thereon, namely claims 17-24, are also found to be directed towards statutory subject matter for at least the same rationale above, and incorporated herein.

Additional clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 1-3, 8, 16-18, 22 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoenberg (6463417) in view of Rozen (6073106) and Rind (Maintaining the confidentiality of medical records shared over the Internet and the World Wide Web, mailed 12/15/2008).

As per claim 1, Schoenberg teaches a method (Title) capable of:

(a) controlling access (reads on “transfer”) to a patient’s medical record (reads on “health information”) (column 2 line 36);

(b) distributing medical records over a network (Abstract);

the method comprising:

(a) receiving, by a database server (reads on “an access server”) (Figure 1 label 122) operatively coupled with a network (Figure 1 label 160), a request to access patient medical record (column 5 line 33-36) over an intranet (reads on “an internal network”) (column 4 line 27), wherein the request is generated by a wireless device capable of displaying patient medical records (reads on “a portable healthcare device”) received over the network (column 4 line 43-46);

(b) providing quick access (reads on "immediately") (column 2 line 18) to the patient records stored in the database (column 5 line 47-48), wherein the server system is capable of:

(i) verifying information entered by the physician to uniquely identify a patient (reads on “if a corresponding consent is stored”) (column 6 line 1-7);

(ii) verifying a plurality of security access codes entered by the physician with respect to a plurality of constraints (reads on "whether the consent satisfies requirements for release of the health information”) (column 6 line 5-13);

(iii) allowing a physician to request access to at least a portion of a patient record (column 5 line 33-36);

(iv) where the security codes were previously set by the patient (column 4 line 52 to column 5 line 32), wherein the system is capable of protecting patient privacy by providing access to the patient's medical record on a need-to-know basis as determined by the patient with the assistance of a physician (reads on "the consent is provided by an owner of the health information") (column 5 line 50-25, line 2-5);

(v) wherein access is provided on a strict need-to-known basis on a granular level, as discussed in (iv) above (reads on "the consent is based on results provided by a filtering component");

(vi) providing information from the categories in which the received security access codes match the assigned security access codes (reads on "a filtering component… such that an unnecessary portion of the health information is filtered out") (column 6 line 15-21).

Schoenberg further teaches that the request to access information is based on a clinical need to protect patient privacy by withholding medically unnecessary patient data (reads on "the request includes an intended purpose of using the health information, wherein the intended purpose is to determine… an appropriateness of the consent") (column 2 line 7-10), wherein the request is a request for a specific a patient record (column 2 line 49-50), wherein the security access codes represent a specific portion of the patient record desired to be viewed by the physician (column 2 line 63 to column 3 line 19).

Schoenberg does not teach:

(a) “the request includes an intended use of the health information, wherein the intended use of the health information of the request is used to determine appropriateness of the consent, or requirements for the consent";

(b) “wherein a purpose field is provided to satisfy intended reasons for which the health information is access in according to the consent".

Rozen teaches:

(a) asking the requestor if the access for emergency or confidential use (reads on “an intended use”), wherein the emergency E-PIN and/or confidential C-PIN is/are entered (reads on “determine... requirements for the consent") and the appropriate set of medical record is provided (reads on "determine... appropriate of the consent") (Figure 1A column 2);

(b) allowing the requestor to input the type of record (e.g. emergency, confidential, both) requested (Figure 1A), wherein access is provided via a website (reads on “a purpose field”) (column 7 line 40-57).

Rozen further teaches that even if the patient is unconscious or otherwise unable to give the E-PIN, an emergency room technician can contact the system, identify the patient, identify himself as an emergency care provider, and be granted access to the patient's emergency information (column 8 line 33-64).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Rozen within the embodiment of Schoenberg with the motivation of providing access to patient data in emergencies (Rozen; column 4 line 17-28).

Rind further teaches (page 2):

> Third, we recognize that in an emergency, it may not be possible to ask a patient for permission to access his or her distant medical record. In this situation and in the absence of a previous statement by the patient forbidding such access, we believe that information may appropriately be released to emergency providers under the doctrine of implied consent [6].

According to Rind, the doctrine of implied consent applies in an emergency wherein the patient is unable to give consent.

At the time the invention was made, according to Rind, it would have been obvious to one of ordinary skill in the art to recognize that the doctrine of implied consent applies in the emergency situation of Schoenberg and Rozen. The skilled artisan would have been motivated by the need to grant access to vital patient records that may save the patient's life in an emergency.

First, Examiner considers the physician requesting access to the emergency information, personal information, or both, to be "an intended use" of the requested information, wherein the intended use of emergency information is for emergency purposes, and the intended use of personal information is to provide comprehensive read/write privileges to the patient's file.

Second, Examiner considers an emergency room technician verifying himself without an E-PIN to obtain access to the patient's file to be "an intended use", wherein the intended use of the technician is to provide emergency services to the patient.

Third, Examiner considers checking the E-PIN, C-PIN, and emergency facility to be "determine appropriateness of consent", wherein the privileges associated with these types of access are checked to determine if sufficient consent exists to accommodate the request.

Fourth, Examiner considers verifying the emergency facility to be "requirements for the consent", wherein E-PIN-less access is only provided to verified emergency facilities.

Schoenberg further teaches:

(a) displaying information in the categories that the physician is authorized to view (Figure 2 label 226);

(b) using a plurality of computer systems (reads on "a health professional device") to access the central database (column 7 line 29-41, Figure 4) to access the patient's medical record (reads on "accessing patient medical history") (column 2 line 16-22).

Insofar as the remainder of the claim is concerned, the applied art need not teach these limitations in view of the optional limitations recited therein.

As per claim 2, Schoenberg teaches that the physician is able to use a wireless device to access the system (column 4 line 43-46).

As per claim 3, Schoenberg teaches notifying the requestor if there are problems with the security codes (Figure 2 label 222).

As per claim 8, Schoenberg teaches determining if the received security access codes satisfy the requester identification constraints (reads on "the suitability of a corresponding consent") (column 6 line 11-13).

As per the set of claim(s): 16, 17, 18, 22, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 1, 2, 3, 8, respectively, and incorporated herein.

In particular, Schoenberg teaches software capable of performing the recited functionality (column 4 line 8-51). See MPEP 2106.01(I).

Claim(s) 4-5, 19-20 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoenberg in view of Rozen and Rind as applied to parent claims 3, 18 above, and further in view of Edelson (5737539).

As per claim 4, Schoenberg, Rozen, and Rind do not teach storing the health information remotely from the server.

Edelson teaches a transient virtual record (Abstract) capable of being stored across a plurality of data warehouses (Figure 16, column 8 line 20 to column 9 line 3).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Edelson within the embodiment of Schoenberg, Rozen, and Rind with the motivation of providing data privacy (Edelson; column 8 line 63 to column 9 line 3).

As per claim 5, Schoenberg teaches using fingerprints (column 5 line 45), retinal scans (column 5 line 44), and security codes (reads on “digital signature data”) (column

6 line 1-20) to identify the patient (reads on "comparing the corresponding consent with stored consent data") (column 5 line 37-45).

Insofar as the remainder of the claim is concerned, the applied art need not teach these limitations in view of the optional limitations recited therein.

As per claim 19, Schoenberg teaches re-authenticating the requestor (Figure 2 label 219, 220, 222).

Schoenberg, Rozen, and Rind do not teach storing the health information remotely.

Edelson teaches a transient virtual record (Abstract) capable of being stored across a plurality of data warehouses (Figure 16, column 8 line 20 to column 9 line 3).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Edelson within the embodiment of Schoenberg, Rozen, and Rind with the motivation of providing data privacy (Edelson; column 8 line 63 to column 9 line 3).

As per the set of claim(s): 20, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 5, respectively, and incorporated herein.

Claim(s) 6, 21 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoenberg in view of Rozen and Rind as applied to parent claims 1, 16 above, and further in view of Snowden (20020026332) and Edelson.

As per claim 6, Schoenberg, Rozen, and Rind do not teach “determining if consent is required".

Snowden teaches accessing anonymous patient data (reads on “determining if consent is required”) (page 7 paragraph 0123).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Snowden within the embodiment of Schoenberg, Rozen, and Rind with the motivation of providing economic benefits (Snowden; page 7 paragraph 0122).

Schoenberg, Rozen, Rind, and Snowden do not teach storing the health information remotely.

Edelson teaches a transient virtual record (Abstract) capable of being stored across a plurality of data warehouses (Figure 16, column 8 line 20 to column 9 line 3).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Edelson within the embodiment of Schoenberg, Rozen, Rind, and Snowden with the motivation of providing data privacy (Edelson; column 8 line 63 to column 9 line 3).

As per the set of claim(s): 21, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 6, respectively, and incorporated herein.

Claim(s) 7 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoenberg in view of Rozen and Rind as applied to parent claim 1 above, and further in view of Applicant Admitted Prior Art (AAPA).

As per claim 7, Schoenberg teaches that the system is capable of being used by any medical care provider requestor (column 2 line 35-39).

Schoenberg, Rozen, and Rind do not teach “a pharmacy benefit manager”.

AAPA teaches PBM's accessing patient data (Specification; page 3 paragraph 0004).

All component parts are known. The only difference is the combination of “old elements” into a single embodiment.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of AAPA within the embodiment of Schoenberg and Rozen, since the operation of the requestor is in no way dependent on medical record system, and a standard requestor may be used with a record system to achieve the predictable result of accessing the data contained therein.

Claims 9-13, 23-24 are rejected under 35 U.S.C. 103(a) as obvious over Schoenberg in view of Rozen as applied to parent claims 1, 16 above as applicable, and further in view of AAPA.

It is noted that the official notice taken in the Office Action mailed 04/02/2008 is taken to be AAPA because Applicant failed to adequately traverse Examiner's assertion.

As per claims 9-10, Schoenberg teaches Internet communication (Figure 1 label 160).

Schoenberg, Rozen, and Rind do not teach “a wrapper for acceptance by a next segment in the network pathway”.

Schoenberg teaches TCP/IP over the Internet (column 4 line 26-27).

AAPA teaches that the Internet is a plurality of interconnected routers, wherein data is routed from a source to a destination based on the TCP/IP protocol, wherein a destination is attached to the data (reads on "a wrapper"). According to the TCP/IP protocol, when a router receives data, the router forwards the data to the next router on the network for delivery to the final destination. At the final destination, the TCP/IP data is dropped, leaving the original data.

All component parts are known. The only difference is the combination of “old elements” into a single embodiment.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of AAPA within the embodiment of Schoenberg, Rozen, and Rind since the operation of the Internet is in no way

dependent on the medical record system, and a standard network communication protocol may be used with a network to achieve the predictable result of transferring data between remote computers.

As per claim 11, Schoenberg teaches a system (Title) comprising:

(a) a server (Figure 1 label 120) comprising:

(i) a data processor (column 4 line 16-24);

(ii) memory capable of storing instructions and results of calculations performed by the data processor (column 4 line 16-24);

(iii) an intranet network interface (reads on “an internal network port) (column 4 line 27);

(iv) a network interface (“a server interface”) (column 4 line 25-29);

(v) software (reads on “a consent processing system”) capable of providing access to patient data based on the level of access granted by the patient (Abstract and throughout), comprising:

(1) a database (reads on “consent database”) (column 3 line 20-20-25);

(2) software (reads on "a search engine") capable of processing request for information by accessing the database (column 3 line 20-49);

(b) the intranet network interface capable of receiving, by a database server (Figure 1 label 122) operatively coupled with a network (Figure 1 label 160), a request to access patient medical record (column 5 line 33-36) over an intranet (column 4 line

27), wherein the request is generated by a wireless device capable of displaying patient medical records (reads on “a portable healthcare device”) received over the network (column 4 line 43-46);

(c) wherein the database is capable of storing access privileges granted by the patient (reads on “consents“) (column 3 line 20-20-25);

(d) wherein the server system is capable of:

(i) verifying information entered by the physician to uniquely identify a patient (reads on “if a corresponding consent is stored”) (column 6 line 1-7);

(ii) verifying a plurality of security access codes entered by the physician with respect to a plurality of constraints (reads on "whether the consent satisfies requirements for release of the health information”) (column 6 line 5-13);

(iii) allowing a physician to request access to at least a portion of a patient record (column 5 line 33-36);

(iv) where the security codes were previously set by the patient (column 4 line 52 to column 5 line 32), wherein the system is capable of protecting patient privacy by providing access to the patient’s medical record on a need-to-know basis as determined by the patient with the assistance of a physician (reads on “the consent is provided by an owner of the health information”) (column 5 line 50-25, line 2-5);

(v) wherein access is provided on a strict need-to-known basis on a granular level, as discussed in (iv) above (reads on "the consent is based on results provided by a filtering component");

(vi) providing information from the categories in which the received security access codes match the assigned security access codes (reads on “a filtering component… such that an unnecessary portion of the health information is filtered out”) (column 6 line 15-21).

Schoenberg further teaches that the request to access information is based on a clinical need to protect patient privacy by withholding medically unnecessary patient data (reads on “the request includes an intended purpose of using the health information, wherein the intended purpose is to determine… an appropriateness of the consent”) (column 2 line 7-10), wherein the request is a request for a specific a patient record (column 2 line 49-50), wherein the security access codes represent a specific portion of the patient record desired to be viewed by the physician (column 2 line 63 to column 3 line 19).

Schoenberg does not teach:

(a) “the request includes an intended use of the health information, wherein the intended use of the health information of the request is used to determine appropriateness of the consent, or requirements for the consent";

(b) “wherein a purpose field is provided to satisfy intended reasons for which the health information is access in according to the consent".

Rozen teaches:

(a) asking the requestor if the access for emergency or confidential use (reads on “an intended use”), wherein the emergency E-PIN and/or confidential C-PIN is/are entered (reads on “determine... requirements for the consent") and the appropriate set

of medical record is provided (reads on "determine... appropriate of the consent") (Figure 1A column 2);

(b) allowing the requestor to input the type of record (e.g. emergency, confidential, both) requested (Figure 1A), wherein access is provided via a website (reads on “a purpose field”) (column 7 line 40-57).

Rozen further teaches that even if the patient is unconscious or otherwise unable to give the E-PIN, an emergency room technician can contact the system, identify the patient, identify himself as an emergency care provider, and be granted access to the patient's emergency information (column 8 line 33-64).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Rozen within the embodiment of Schoenberg with the motivation of providing access to patient data in emergencies (Rozen; column 4 line 17-28).

Rind further teaches (page 2):

> Third, we recognize that in an emergency, it may not be possible to ask a patient for permission to access his or her distant medical record. In this situation and in the absence of a previous statement by the patient forbidding such access, we believe that information may appropriately be released to emergency providers under the doctrine of implied consent [6].

According to Rind, the doctrine of implied consent applies in an emergency wherein the patient is unable to give consent.

At the time the invention was made, according to Rind, it would have been obvious to one of ordinary skill in the art to recognize that the doctrine of implied consent applies in the emergency situation of Schoenberg and Rozen. The skilled artisan would have been motivated by the need to grant access to vital patient records that may save the patient's life in an emergency.

First, Examiner considers the physician requesting access to the emergency information, personal information, or both, to be "an intended use" of the requested information, wherein the intended use of emergency information is for emergency purposes, and the intended use of personal information is to provide comprehensive read/write privileges to the patient's file.

Second, Examiner considers an emergency room technician verifying himself without an E-PIN to obtain access to the patient's file to be "an intended use", wherein the intended use of the technician is to provide emergency services to the patient.

Third, Examiner considers checking the E-PIN, C-PIN, and emergency facility to be "determine appropriateness of consent", wherein the privileges associated with these types of access are checked to determine if sufficient consent exists to accommodate the request.

Fourth, Examiner considers verifying the emergency facility to be "requirements for the consent", wherein E-PIN-less access is only provided to verified emergency facilities.

Schoenberg further teaches displaying information in the categories that the physician is authorized to view (Figure 2 label 226) over the Internet (column 2 line 60-61). Schoenberg further teaches TCP/IP over the Internet (column 4 line 26-27).

AAPA teaches that the Internet is a plurality of interconnected routers, wherein data is routed from a source to a destination based on the TCP/IP protocol, wherein a destination is attached to the data (reads on "a wrapper"). According to the TCP/IP protocol, when a router receives data, the router forwards the data to the next router on

the network for delivery to the final destination. At the final destination, the TCP/IP data is dropped, leaving the original data.

All component parts are known. The only difference is the combination of "old elements" into a single embodiment.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of AAPA within the embodiment of Schoenberg and Rozen, since the operation of the Internet is in no way dependent on the medical record system, and a standard network communication protocol may be used with a network to achieve the predictable result of transferring data between remote computers.

Schoenberg further teaches:

(a) using a plurality of computer systems (reads on "a health professional device") to access the central database (column 7 line 29-41, Figure 4) to access the patient's medical record (reads on "accessing patient medical history") (column 2 line 16-22).

Insofar as the remainder of the claim is concerned, the applied art need not teach these limitations in view of the optional limitations recited therein.

As per the set of claim(s): 12, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 8, respectively, and incorporated herein.

As per claim 13, this claim is rejected for substantially the same rationale as applied to claim 9 above, and incorporated herein.

In particular, Schoenberg teaches using the Internet to route data between the database and the requestor (Figure label 160).

As per the set of claim(s): 23, 24, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 9, 10, respectively, and incorporated herein.

Claims 14-15 are rejected under 35 U.S.C. 103(a) as obvious over Schoenberg in view of Rozen, Rozen, and AAPPA as applied to parent claim 11 above, and further in view of de la Huerga (5903889).

As per claims 14-15, Schoenberg, Rozen, Rind, and AAPA do not teach determining the type of information received and determining an appropriate software application program therefor.

De la Huerga teaches processing patient data based on the data type of the patient data (column 3 line 55-65).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of de la Huerga within the embodiment of Schoenberg, Rozen, Rind, and AAPA with the motivation of providing interoperability (de la Huerga; column 1 line 53-65).

Response to Arguments

Applicant's arguments filed 12/30/2008 have been fully considered but they are not persuasive.

As discussed above, Applicant does not point out support the newly added limitations.

Applicant is requested to specifically point out support for the added limitations in the specification as originally filed on 01/04/2002.

Additionally, for new or amended claims, it is not enough to specifically point out that the claimed features were originally disclosed.

MPEP 2163(I)(B) reads as follows:

"While there is no *in haec verba* requirement, **newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure**".

MPEP 2163.02 reads as follows:

"An applicant shows possession of the claimed invention by **describing the claimed invention with all of its limitations** using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines*, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997)".

To clarify the record, Applicant is suggested to refer to the specification as originally file to provide support for the claimed embodiment in its entirety, including discussing how all the claimed features were originally described in a single embodiment via express, implicit, or inherent support.

Applicant is reminded that mere original disclosure of a claim feature is not enough to meet the written description requirement for amended claims. The specification as originally filed must provide support for the claimed embodiment with no manipulation required thereof.

Any modification, obvious or otherwise, of the original disclosure required to arrive at the claimed invention would render the added features new matter.

To properly point out support for the claim in the specification as originally filed, Applicant is suggested to discuss how the specification as originally filed is anticipatory of the entire new or amended claim, including all claim features, in a single embodiment with no modification required of the specification.

As per claim 1, on page 10-11 Applicant argues:

Referring now to the section relied upon by the Examiner (for a particular feature of claim1), Schoenberg further discloses "if the patient suffers a broken bone, *while information regarding the patient's blood type and allergies might be necessary for the proper treatment of the injury, the patient's cardiological or serological data is not. None of the above methods can prevent unnecessary medical data from being divulged to the medical care provider, thus potentially risking the patient's privacy.*" (col. 2, lines 7-10; emphasis added). This is not the same as "the request includes an intended use of the health information, wherein the intended use is to determine one or more of appropriateness of the consent, and requirements for the consent, wherein a purpose field is provided to specify intended reasons for which the health information is accessed in

according to the consent" as recited by claim 1 (emphasis added). Schoenberg does not teach or reasonably suggest at least these features of claim 1.

The Examiner acknowledges that Schoenberg does not teach or reasonably suggest all the limitations of claim 1, such as the intended use of the health information of the request is used to determine appropriateness of the consent or requirements for the consent, wherein a purpose field is provided to specify intended reasons for which the health information is accessed according to the consent as recited by claim 1. (see page 5, Office Action, mailed 12-15-08).

Examiner agrees with Applicant's characterization of the rejection. Page 5 of the previous Office Action reads as follows:

Schoenberg further teaches that the request to access information is based on a clinical need to protect patient privacy by withholding medically unnecessary patient data (reads on "the request includes an intended purpose of using the health information, wherein the intended purpose is to determine... an appropriateness of the consent") (column 2 line 7-10), wherein the request is a request for a specific a patient record (column 2 line 49-50), wherein the security access codes represent a specific portion of the patient record desired to be viewed by the physician (column 2 line 63 to column 3 line 19).

Schoenberg does not teach:

(a) "the request includes an intended use of the health information, wherein the intended use of the health information of the request is used to determine appropriateness of the consent, or requirements for the consent";

(b) "wherein a purpose field is provided to satisfy intended reasons for which the health information is access in according to the consent".

Accordingly, the previous Office Action specifically pointed out that the goal of Schoenberg was to provide physicians access to only medically relevant portions of a patient's record, and to prevent physicians from accessing those portions of the patient record that are irrelevant, and should be protected from view.

The portion cited by Applicant in the argument regarding Schoenberg (column 2) discloses:

> if the patient suffers a broken bone, while information regarding the patient's blood type and allergies might be necessary for the proper treatment of the injury, the patient's cardiological or serological data is not. None of the above methods can prevent unnecessary medical data from being divulged to the medical care provider, thus potentially risking the patient's privacy.

Accordingly, Schoenberg discusses the general state of the art wherein physicians should be provided access to only specific portions of the medical record, and other portions of the record should be protected. Additionally, Schoenberg discusses the flaws of the prior art. Schoenberg then goes on to present his contribution to the art by allowing physicians to access only relevant certain portions of the patient record.

On page 11 Applicant further argues:

For example, Rozen discloses "*[v]ia Internet communications or via phone/fax/mail*, a participant is prompted to provide a constant identifier and a selected password. Emergency and confidential categories of medical information are identified, and the ***participant is prompted to provide personal information in each of the categories and a different personal identification numbe***r (E-PIN, C-PIN) for each category." (Abstract; emphasis). Rozen's managing and controlling access information is **not the same as** the intended use of the health information of the request is used to determine appropriateness of the consent or requirements for the consent, wherein a purpose field is provided to specify intended reasons for which the health information is accessed according to the consent as recited by claim 1.

Page 5-7 of the previous Office Action thoroughly discussed the rationale for obviousness as suggested by the applied art. See also above.

Specifically, Applicant did not address the feature of waiving the E-PIN/C-PIN for an emergency personnel to obtain the patient record in the event of an emergency, as taught by Rozen and recognized by Rind to be implied consent.

On page 11-12 Applicant further argues:

Claim 1, as amended, further recites "electronically communicating the health information between the portable healthcare device and a health professional device, wherein communicating the health information includes one or more of prescribing prescriptions, accessing patient medical history, accessing medical test results, submitting order claims, purchasing medicine". (emphasis added). Schoenberg, Rozen and Rind,

neither individually nor when combined, teach or reasonably suggest at least this feature of claim 1.

Schoenberg teaches (column 7):

> While the invention has been described as including one setup system that accesses the server system, a plurality of setup systems may be coupled to the server system in order to allow patients at different locations to access the server system. Such a configuration is illustrated in FIG. **4**. In this system **300**, in addition to the setup system **110**, a second server system **140** is coupleable to the server system **120** over communications network **160** for the purpose distributing medical information in the manner described above. It will be understood that the server system can be accessed through any number of setup systems, and that any number of request systems may access the server system in the manner described above.

Schoenberg further teaches:

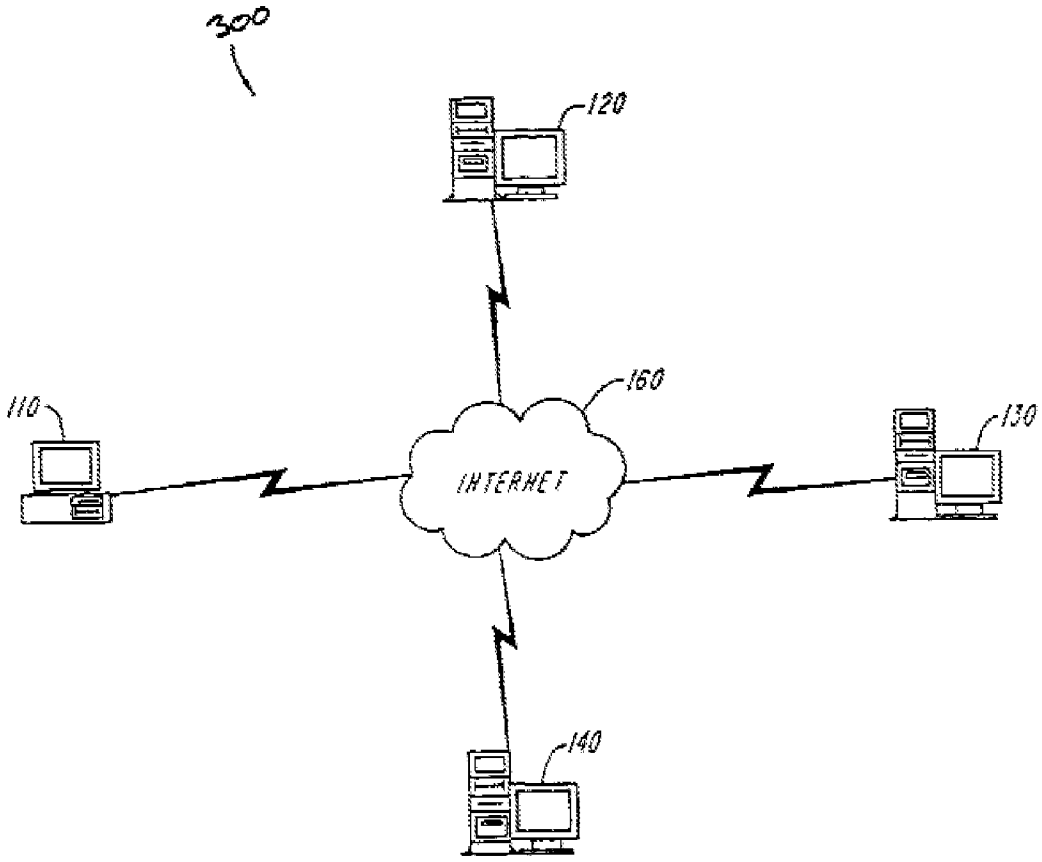

FIG. 4

Schoenberg further teaches (column 2):

Accordingly, it is an object of this invention to provide a method of and system for distributing medical information in which the medical care provider has quick access to a patient's medical record, but only to the information within the medical record that is necessary for the proper treatment of the patient at that time.

According to Schoenberg, a plurality of computers may be used to access the patient's medical record, and is considered to be "accessing patient medical history".

Insofar as the remainder of the claim is concerned, the applied art need not teach these limitations in view of the optional limitations recited therein.

Conclusion

The new ground(s) of rejection presented in this Office action, if any, was/were necessitated by Applicant's amendment. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran (Ken) N. Nguyen whose telephone number is 571-270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. N./
Examiner, Art Unit 3626
02/12/2008

/Robert Morgan/
Primary Examiner, Art Unit 3626